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*a Systematic Review and Meta-Analysis*

Starch-Jensen, Thomas; Deluiz, Daniel; Duch, Kirsten; Tinoco, Eduardo Muniz Barretto

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# Maxillary Sinus Floor Augmentation With or Without Barrier Membrane Coverage of the Lateral Window: a Systematic Review and Meta-Analysis

Thomas Starch-Jensen<sup>1</sup>, Daniel Deluiz<sup>2</sup>, Kirsten Duch<sup>3</sup>, Eduardo Muniz Barretto Tinoco<sup>2</sup>

<sup>1</sup>Department of Oral and Maxillofacial Surgery, Aalborg University Hospital, Aalborg, Denmark

<sup>2</sup>Department of Periodontology, Rio de Janeiro State University, Rio de Janeiro, Brazil.

<sup>3</sup>Unit of Clinical Biostatistics, Aalborg University Hospital, Aalborg, Denmark.

## Corresponding Author:

Thomas Starch-Jensen

Department of Oral and Maxillofacial Surgery

Aalborg University Hospital

18-22 Hobrovej, DK-9000 Aalborg

Denmark

Phone: +45 97 66 27 98

Fax: +45 97 66 28 25

E-mail: [thomas.jensen@rn.dk](mailto:thomas.jensen@rn.dk)

## ABSTRACT

**Objectives:** Test the hypothesis of no difference in implant treatment outcomes after maxillary sinus floor augmentation with or without barrier membrane coverage of the lateral window.

**Material and Methods:** A MEDLINE (PubMed), Embase and Cochrane library search in combination with a hand-search of relevant journals was conducted. Human studies published in English until the 5<sup>th</sup> of July, 2019 were included. Randomised controlled trials and controlled trials with an observation period of minimum six months were included. Primary outcomes included survival of suprastructures and implants. Secondary outcomes included implant stability quotient, peri-implant marginal bone loss, bone regeneration, patient-reported outcome measures, biologic and mechanical complications.

**Results:** The electronic search and hand-searching resulted in 1068 entries. Six randomised controlled trials characterised by low to high risk of bias and one controlled trial with high risk of bias fulfilled the inclusion criteria. High implant survival rate was reported with both treatment modalities. Meta-analyses disclosed a mean difference of newly formed bone of 6.4% (confidence interval = 0 to 12.9) and non-mineralised tissue of -1.1% (confidence interval = -2.7 to 0.5), indicating more newly formed bone and diminished non-mineralised with barrier membrane coverage.

**Conclusions:** There seem to be no statistically significant differences in implant treatment outcomes after maxillary sinus floor augmentation with or without barrier membrane coverage of the lateral window. However, barrier membrane coverage increases percentage of newly formed bone and diminishes proliferation of non-mineralised tissue. Thus, barrier membrane coverage seems to be beneficial and also preventing displacement of the grafting material.

**Keywords:** alveolar ridge augmentation; dental implants; oral surgical procedures; review; sinus floor augmentation.

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## INTRODUCTION

Maxillary sinus floor augmentation (MSFA) applying the lateral window technique is the most commonly used surgical procedure to increase the alveolar bone height of the posterior maxilla before or in conjunction with implant placement, and the treatment outcome involving different types of grafting materials have been documented in several systematic reviews and meta-analyses [1-8]. Barrier membrane coverage of the lateral window has been recommended to prevent soft tissue interference and improve bone regeneration as well as stabilisation of the grafting material [9-11]. However, barrier membrane coverage of the lateral window is associated with lower vascular supply to the applied grafting material, increased risk of infection and additional cost. Moreover, non-absorbable membranes have to be removed and occasionally lead to complications such as wound dehiscence [11]. Systematic reviews have demonstrated high implant survival rate after MSFA with barrier membrane coverage of the lateral window [12-15]. In addition, increased percentage of vital bone after graft maturation have also been reported with barrier membrane coverage compared with the use of no barrier membrane coverage [16,17]. However, further systematic reviews and meta-analyses have concluded that the implant survival rate and amount of vital bone formation were not influenced by barrier membrane coverage [18-21]. Consequently, the effectiveness of barrier membrane coverage of the lateral window in conjunction with MSFA remains disputable. The rationale for this systematic review is therefore to investigate whether barrier membrane coverage of the lateral window in conjunction with MSFA is necessary since the use of a barrier membrane increases the cost of the treatment and involves a risk of contamination and disease transmission as well as they can be refused by patients for religious reasons or because they are in contrast with chosen lifestyle.

The objective of the present systematic review and meta-analysis is therefore to test the hypothesis of no difference in implant treatment outcomes after MSFA with or without barrier membrane coverage of the lateral window.

## MATERIAL AND METHODS

### Protocol and registration

The present systematic review was conducted in accordance with the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) statement for reporting systematic reviews [22]. The PRISMA checklist is outlined in [Appendix 1](#). The methods of analysis and inclusion criteria were specified in advance and documented in a protocol. The review was registered in PROSPERO, an international prospective register of systematic reviews. Registration number: CRD42019139519.

The protocol can be accessed at:

[https://www.crd.york.ac.uk/prospero/display\\_record.php?ID=CRD42019139519](https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42019139519).

### Focus question

The focus question was developed according to the Patient, Intervention, Comparison and Outcome (PICO) framework as described in Table 1.

Focus question: Are there any differences in implant treatment outcomes after MSFA with or without barrier membrane coverage of the lateral window?

### Types of studies and publications

The present systematic review included randomised controlled trials and controlled trials on humans.

### Population

The included studies of the present systematic review involved healthy adult partially or totally edentulous

**Table 1.** PICOS guidelines

<b>Patient and population (P)</b>	Healthy adult patients with atrophy of the posterior part of the maxilla receiving maxillary sinus floor augmentation applying the lateral window technique.
<b>Intervention (I)</b>	Barrier membrane coverage of the lateral window.
<b>Comparator or control group (C)</b>	No barrier membrane coverage of the lateral window.
<b>Outcomes (O)</b>	Primary outcomes included survival of suprastructures and implants. Secondary outcomes included implant stability quotient, peri-implant marginal bone loss, bone regeneration, patient-reported outcome measures, biologic and mechanical complications.
<b>Study design (S)</b>	Randomised controlled trials and controlled trials with an observation period of minimum six months.
<b>Focused question</b>	Are there any differences in implant treatment outcomes after maxillary sinus floor augmentation with or without barrier membrane coverage of the lateral window?

patients with atrophy of the posterior part of the maxilla receiving MSFA applying the lateral window technique with or without barrier membrane coverage.

### Types of outcome measures

The primary outcome measures are the most important measures for evaluating of the final implant treatment outcomes. Secondary, outcome measures were also included in the present systematic review as surrogate measures.

The primary outcome measures included:

- Survival of suprastructures. Loss of suprastructure was defined as a total loss because of a mechanical and/or biological complication.
- Survival of implants. Loss of implants was defined as mobility of previously clinically osseointegrated implants and removal of non-mobile implants due to progressive peri-implant marginal bone loss and infection.

Moreover, the following secondary outcome measures were assessed:

- Implant stability quotient. Estimated by resonance frequency analysis.
- Peri-implant marginal bone loss. Evaluated by radiographic measurements.
- Bone regeneration. Percentage of newly formed bone, non-mineralized tissue and residual graft material as evaluated by radiographic or histologic measurements.
- Patient-reported outcome measures.
- Biologic and mechanical complications.

### Information sources

The search strategy incorporated examinations of electronic databases, supplemented by a thorough hand-search page by page of relevant journals including “British Journal of Oral and Maxillofacial Surgery”, “Clinical Implant Dentistry and Related Research”, “Clinical Oral Implants Research”, “European Journal of Oral Implantology”, “Implant Dentistry”, “International Journal of Oral and Maxillofacial Implants”, “International Journal of Oral and Maxillofacial Surgery”, “International Journal of Periodontics and Restorative Dentistry”, “International Journal of Prosthodontics”, “Journal of Clinical Periodontology”, “Journal of Dental Research”, “Journal of Oral Implantology”, “Journal of Oral & Maxillofacial Research”, “Journal of Periodontology”, “Journal of Prosthetic Dentistry”, “Journal of Craniofacial Surgery”, “Journal of Cranio-Maxillo-Facial Surgery”, “Journal of Oral

and Maxillofacial Surgery”, “Periodontology 2000”, “Oral and Maxillofacial Surgery” and “Oral Surgery Oral Medicine Oral Pathology Oral Radiology”. The manual search also included the bibliographies of all articles selected for full-text screening as well as previously published reviews relevant for the present systematic review.

### Search

A MEDLINE (PubMed), Embase, and Cochrane Library search was conducted. Human studies published in English until the 5<sup>th</sup> of July, 2019 were included. The search strategy was performed in collaboration with a librarian and utilized a combination of Medical subject heading (MeSH) and free text terms. The search strategy is outlined in [Appendices 2, 3 and 4](#).

### Selection of studies

The titles of the identified reports were initially screened. The abstract was assessed when the title indicated that the study was relevant. Full-text analysis was obtained for those with apparent relevance or when the abstract was unavailable. The references of the identified papers were cross-checked for unidentified articles.

### Study eligibility

The inclusion criteria were developed using the PICOS guidelines (Table 1).

### Inclusion criteria

The review exclusively focused on studies with an observation period of minimum six months after MSFA. In addition, at least five patients should be included in the study and the number of sinus augmentation procedures must be clearly specified.

### Exclusion criteria

Studies with implant placement in medically compromised patients as well as studies with insufficient description of the performed numbers of surgical procedures or length of observation period were excluded. Moreover, letters, editorials, PhD theses, letters to the editor, case reports, abstracts, technical reports, conference proceedings, animal or *in vitro* studies and literature review papers were also excluded.

## Data extraction

Data were extracted according to a data-collection form ensuring systematic recording of the outcome measures. In addition, relevant characteristics of the study were recorded. The corresponding author was contacted by e-mail in the absence of important information or uncertainties.

## Data items

The following items were collected from the included articles and arranged in the following fields: author, year of publication, study design, number of patients, MSFA procedures, residual alveolar bone height, type of grafting material, membrane, number of implants, prosthetic solution, length of observation period, survival of suprastructure and implants, implant stability quotient, peri-implant marginal bone loss, bone regeneration, biologic and mechanical complications.

## Assessment of methodological quality

The quality assessment of the included studies was undertaken as part of the data extraction process. A methodological quality rating system was used and the classification of the risk of bias potential for each study was based on the following five criteria [1,2]:

1. Random selection in the population (yes/no).
2. Definition of inclusion, exclusion criteria (yes/no).
3. Report of losses to follow-up (yes/no).
4. Validated measurements (yes/no).
5. Statistical analysis (yes/no).

The studies were grouped according to:

1. Low risk of bias (plausible bias unlikely to seriously alter the results) if all above-described quality criteria were met.
2. Moderate risk of bias (plausible bias that weakens confidence in the results) when one of these criteria were not included.
3. High risk of bias (plausible bias that seriously weakens confidence in the results) when two or more criteria were missing.

## Statistical analysis

Meta-analyses were to be conducted only if there were studies of similar comparison, reporting identical outcome measures. However, the included studies of the meta-analysis revealed variations in study design, i.e. size of the lateral window, residual height of the alveolar process, dimension of the sinus cavity, use of nonresorbable and resorbable membranes, dissimilar

grafting material, bone cores for histomorphometric analysis were retrieved at different locations, types of outcome measures, length of the graft healing period and observation period. Therefore, a well-defined meta-analysis was not applicable. However, the percentage of newly formed bone and non-mineralised tissue across comparable studies were analysed in a meta-analysis. Forest plots were drawn to show a summary of the histomorphometric characteristics and expressed as the mean difference (MD) between MSFA with barrier membrane coverage of the lateral window and without barrier membrane coverage with the mean expressed in percentage. The 95% confidence interval (CI) was also calculated. Parametric data were expressed as mean and standard deviation (M [SD]). Statistical significance level was defined at  $P = 0.05$ .

## Assessment of heterogeneity

The significance of any discrepancies in the estimates of the treatment effects of the different studies was assessed by means of Cochran's test for heterogeneity and the  $I^2$  statistic, which describes the percentage of total variation across studies that is due to heterogeneity rather than chance. Heterogeneity was considered statistically significant if  $P < 0.1$ . A rough guide to the interpretation of  $I^2$  given in the Cochrane Handbook for Systematic Reviews of Interventions is as follows: (1) at 0 - 40% the heterogeneity might not be important, (2) 30 - 60% may represent moderate heterogeneity, (3) 50 - 90% may represent substantial heterogeneity, and (4) 75 - 100% may represent considerable heterogeneity [23].

## RESULTS

### Study selection

Article review and data extraction were performed according to the PRISMA flow diagram (Figure 1). The electronic search resulted in 1067 entries. One article was identified through hand-searching [16]. Of these 1068 articles, 427 were excluded because they had been retrieved in more than one search. A total of 31 abstracts were reviewed and full-text analysis included 12 articles. Finally, seven studies were included in the present systematic review [16,17, 24-28].

### Exclusion of studies

The reasons for excluding studies after full-text assessment were as follows: retrospective study



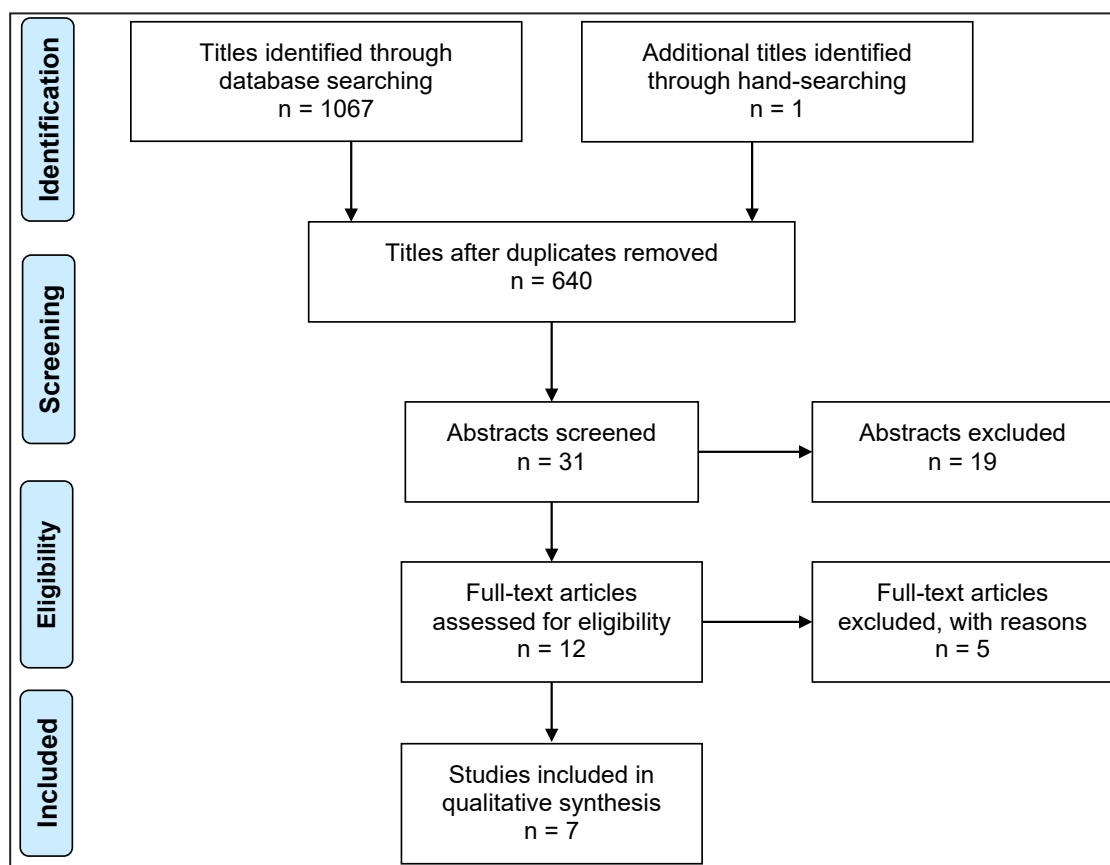


Figure 1. PRISMA flow diagram demonstrating the results of the systematic literature search.

without a control group [29], MSFA with two-window technique [30]. Moreover, three studies could not be excluded before meticulous reading [31-33].

### Study characteristics

The included studies of the present systematic review consisted of six randomised controlled trials [16,17,24,26-28] and one controlled clinical trial [25]. A split-mouth study design was used in three randomized controlled trials [17,26,28]. Partially and totally edentulous patients with horizontal deficiencies of the maxillary alveolar ridge were enrolled in the included studies. No significant difference in patient demographics were reported in two studies [27,28]. Inclusion and exclusion criteria were specified in all the included studies [16,17,24-28]. Patients with controlled diabetes were not excluded in three studies [16,17,25] and smoking habits were not excluded in six studies [16,17,24,25,27,28]. The residual bone height was described in three studies [24,27,28]. Power calculation was performed in one study [28]. CONSORT guidelines were followed in one study [27]. Randomisation was conducted using a computer generated random allocation process [27,28] or no information was provided about the randomisation procedure [16,17,24,26]. The surgical procedure was

performed by the same surgeon [28], two surgeons [27] or no information was provided about the number of surgeons involved in the study [16,17,24-26]. Dimension of the lateral window was measured in one study [27]. Various grafting materials were used involving OsteoGraf/N® (CeraMed, Lakewood, Colorado, USA) alone or in combination with varying percentages of autogenous bone or demineralized freeze-dried bone allograft [16], Bio-Oss® (Geistlich Pharma AG, Wolhusen, Switzerland) [24,28], Bio-Oss® (Osteohealth Co., Shirley, NY, US) alone or in combination with a maximum of 20% autogenous bone graft from the maxillary tuberosity or ascending mandibular ramus [25], mixture of 50% particulated autogenous bone graft from the lateral bone wall and 50% collagenated corticocancellous porcine bone (MP3®; Osteobiol-Tecnoss, Coazze, Italy) [27], Bio-Oss® (Osteohealth, Newport Beach, California, USA) [26] or various grafting materials [17]. Different barrier membranes were used to cover the lateral window involving non-resorbable expanded polytetrafluoroethylene (e-PTFE) membrane (Goretex Augmentation Material, 3i, W. L. Gore) [16,17,25] or resorbable collagen Bio-Gide® membrane (Geistlich Pharma AG, Wolhusen, Switzerland) [24,28], Bio-Gide® membrane (Osteohealth Co., Shirley, New York, USA) [25] (Osteohealth, Newport Beach,

California, USA) [26], and Evolution (Osteobiol-Tecnoss, Torino, Italy) [27]. Fixation of the covering barrier membrane was conducted in six studies [16,17,24-26,28]. Frios® tacks (Friadent GmbH, Mannheim, Germany) were used in one study [24], while no information was provided in five studies about the used tacks [16,17,25,26,28]. MSFA with delayed implant placement were performed in three studies after 6 to 10 months of graft healing [25-27]. MSFA involving both immediate and delayed implant placement was performed in four studies [16,17,24,28]. Different implant systems were used including screw-type machined-surface implants (Brånemark System®; Nobel Biocare, Gothenburg, Sweden) [24] and Osseotite® (Biomet 3i Inc., Palmbeach, Florida, USA) [28]. The used implant system was not specified in five studies [16,17,25-27]. Histomorphometric parameters were assessed in six studies [16,25-28], after six months [27,28], 6 to 9 months [16], 6 to 10 months [25], eight months [26] or 7 to 13 months [17], respectively. The bone cores were retrieved with trephine drill through the previous lateral window [16,17,25-27] or at implant placement sites [28]. None of the included studies provided information about training or calibration of the examiners assessing the clinical and radiographic outcome. Information about blinding assessment was described in one study [28]. Numbers of drop outs were described in two studies [26,27]. Survival of suprastructures, implant stability quotient, peri-implant marginal bone loss and patient-reported outcome measures was not reported in any of the included studies. Thus, these outcome measures are not described in the following section or outlined in Table 2.

## Outcome measures

The result of each outcome measure is presented first and then a short summary is finally provided. The results of the outcome measures are outlined in Table 2.

### Survival of implants

Survival of implants with a non-resorbable covering barrier membrane (e-PTFE) was 99% compared with 96% without a membrane [16]. No statistical analysis was performed [16].

Survival of implants with a non-resorbable covering barrier membrane (e-PTFE) was 100% compared with 93% without a membrane, after 0 to 5 years [17]. No statistical analysis was performed [17].

Survival of implants with a resorbable covering

collagen barrier membrane (Bio-Gide®) was 93% compared with 78% without a membrane, after 12 - 40 months [24]. No statistical analysis was performed. There was no difference in implant failure rate between MSFA with immediate or delayed implant placement when membrane coverage of the lateral window was performed. While, an increased implant failure rate was reported after MSFA and immediate implant placement without barrier membrane coverage of the lateral window [24].

Survival of implants after MSFA with a resorbable collagen covering barrier membrane (Bio-Gide®) or a non-resorbable covering barrier membrane (e-PTFE) was 98% compared with 100% without a membrane, after one year of functional implant loading [25]. No statistical analysis was performed [25].

Survival of implants after MSFA with a resorbable covering collagen barrier membrane (Bio-Gide®) was 96% compared with 94% without a membrane, after one year of functional implant loading [28]. There was no statistically significant difference in implant survival rate between the two treatment modalities ( $P = 0.08$ ). However, immediate implant placement revealed a statistically significant higher implant failure rate compared with delayed implant placement ( $P = 0.04$ ) [28].

### Summary

MSFA with or without barrier membrane coverage of the lateral window seems not to significantly influence the implant survival rate. However, a higher percentage of implant failures were reported after MSFA without barrier membrane coverage and immediate implant placement.

### Bone regeneration

Percentage of newly formed bone after MSFA with a non-resorbable covering barrier membrane (e-PTFE) varied between 17 - 33% compared with 9 - 19% without a membrane, after 6 to 9 months [16]. No statistical analysis was performed [16].

Percentage of newly formed bone after MSFA with a non-resorbable covering barrier membrane (e-PTFE) was 26 (15)% compared with 11 (8)% without a membrane, after 7 to 13 months [17]. No statistical analysis was performed [17].

Percentage of newly formed bone, non-mineralised tissue and residual graft material after MSFA with a non-resorbable covering barrier membrane (e-PTFE) was 17%, 51% and 32%, after 6 to 10 months, respectively [25]. Resorbable covering collagen barrier membrane (Bio-Gide®) revealed 18%, 56% and 26%.

**Table 2.** Maxillary sinus floor augmentation with or without barrier membrane coverage of the lateral window

Study	Year of publication	Study design	NOP	Materials and methods							Outcome measures				
				MSFA	RBH (mm)	Type of grafting material	Membrane	Number of implants	Prosthetic solution	LOP (month)	Survival of implants (%)	Bone regeneration (%)			Biologic and mechanical complications
												NFB	NMT	RG	
Froum et al. [16]	1998	RCT	113	113	NR	Combination of different grafting materials	e-PTFE: 79	133	NR	6 - 9	99	17 - 33	NR	NR	
							No membrane coverage: 34	82			96	9 - 19			
Tarnow et al. [17]	2000	RCT, split-mouth	12	12	NR	Combination of different grafting materials	e-PTFE: 12	28	NR	7 - 13	100	26 (SD 15)	NR	NR	
							No membrane coverage: 12	27			93	12 (SD 8)			
Tawil et al. [24]	2001	RCT	29	30	4 - 8	Bio-Oss®: 100%	Collagen membrane: 15	29	Fixed prostheses	22.4 (12 - 40)	93	NR			Mucosal tears: 5
							No membrane coverage: 15	32			78				
Wallace et al. [25]	2005	CCT	51	21	NR	Bio-Oss®: 100%; PABG: 20% and Bio-Oss®: 80%	e-PTFE: 21	46	NR	12	98	17	51	32	NR
				37			Collagen membrane: 37	83			98	18	56	26	
				6			No membrane coverage: 6	6			100	12	64	24	
Choi et al. [26]	2009	RCT, split-mouth	6	12	NR	Bio-Oss®: 100%	Collagen membrane: 6	NR	NR	8 (7 - 9)	NR	13 <sup>a</sup>	36 <sup>b</sup>	50 <sup>c</sup>	None
							No membrane coverage: 6					12	55	33	Dehiscence: 1; swelling: 1
Barone et al. [27]	2013	RCT	18	18	< 5	PABG: 50%; MP3®: 50%	Collagen membrane: 9	NR	NR	6	NR	31 (SD 16)	51 (SD 19)	18 (SD 20)	SMP: 1; dehiscence: 1; haematoma: 2
							No membrane coverage: 9					28 (SD 19)	59 (SD 15)	13 (SD 12)	SMP: 2; dehiscence: 1; haematoma: 2
García-Denche et al. [28]	2013	RCT, split-mouth	109	66	4 - 7	Bio-Oss®: 100%	Collagen membrane: 66	278	Fixed prostheses or bar retention	12	96.1 <sup>d</sup>	19 (SD 6) <sup>e</sup>	31 (SD 3) <sup>f</sup>	49 (SD 10) <sup>g</sup>	None
				69			No membrane coverage: 69				94.2	15 (SD 5)	32 (SD 6)	56 (SD 21)	Displacement of grafting material: 4

<sup>a</sup>P = 0.937 (nonparametric Mann-Whitney U test); <sup>b</sup>P = 0.026 (nonparametric Mann-Whitney U test); <sup>c</sup>P = 0.093 (nonparametric Mann-Whitney U test); <sup>d</sup>P = 0.08 (Cohen's  $f^2$  test); <sup>e</sup>P = 0.52 (non-parametric Wilcoxon t-test); <sup>f</sup>P = 1 (non-parametric Wilcoxon t-test); <sup>g</sup>P = 0.6 (non-parametric Wilcoxon t-test).

CCT = controlled clinical trial; e-PTFE = expanded polytetrafluoroethylene; LOP = length of observation period; MSFA = maxillary sinus floor augmentation; NFB = newly formed bone; NMT = non-mineralised tissue; NOP = number of patients; PABG = particulated autogenous bone graft; PIMBL = peri-implant marginal bone loss; RCT = randomised controlled trial; RG = residual graft; SMP = sinus membrane perforation; SD = standard deviation.



Corresponding measurements for no barrier membrane coverage was 12%, 64% and 24%. No statistical analysis was performed, but a higher percentage of newly formed bone and diminished percentage of non-mineralised tissue was observed after MSFA with barrier membrane coverage of the lateral window [25].

Percentage of newly formed bone, non-mineralised tissue and residual graft material after MSFA with a resorbable covering collagen barrier membrane (Bio-Gide®) was 13%, 36% and 50%, after eight months, respectively [26]. Corresponding measurements without a membrane was 12%, 55% and 33%. There were no statistically significant differences in the new bone formation ( $P = 0.937$ ) and residual grafting material ( $P = 0.093$ ) after MSFA with or without barrier membrane coverage of the lateral window. However, the average percentage of non-mineralised tissue was statistically significant higher without barrier membrane coverage ( $P = 0.026$ ) compared with barrier membrane coverage of the lateral window [26].

Percentage of newly formed bone, non-mineralised tissue and residual graft material after MSFA with a resorbable covering collagen barrier membrane (Evolution) was 31 (16)%, 51 (19)% and 18 (20)%, after six months, respectively [27]. Corresponding measurements without a membrane was 28 (19)%, 59 (15)% and 13 (12)%. There was no statistically significant difference in the histomorphometric outcome after MSFA with or without barrier membrane coverage of the lateral window ( $P = 0.82$ ), but a decreased percentage of non-mineralised tissue was observed with barrier membrane coverage [27].

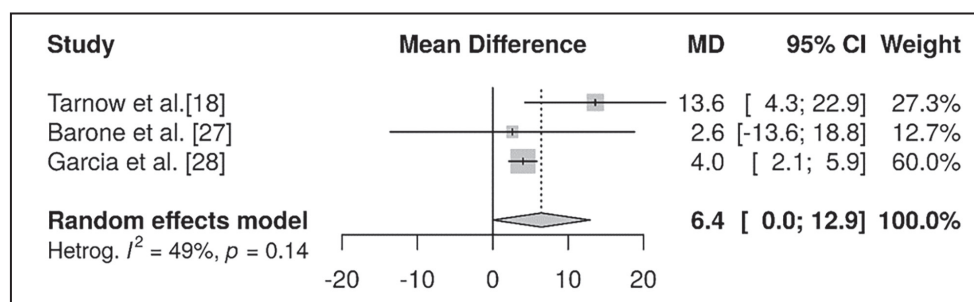
Percentage of newly formed bone, non-mineralised tissue and residual graft material after MSFA with a covering barrier membrane (Bio-Gide®) was 19 (6)%, 31 (3)% and 49 (10)%, after six months, respectively [28]. Corresponding measurements without a membrane was 15 (5)%, 32 (6)% and 56 (21)%. There was no statistically significant difference in newly formed bone ( $P = 0.52$ ), non-mineralised tissue ( $P = 1$ ) or residual graft material ( $P = 0.6$ ) [28].

## Meta-analysis

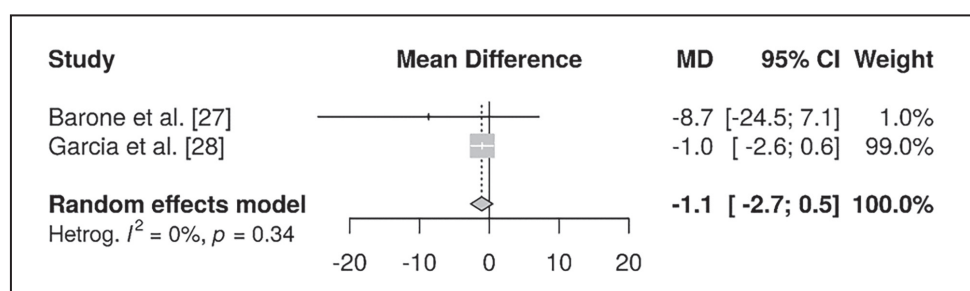
Meta-analysis (with random effect) where conducted to combine data from multiple studies where similar effects were measured. However meta-analysis can only be conducted for continuous data if both the mean and standard deviation (SD) are available of the percentage of newly formed bone and non-mineralised tissue. Thus only three studies [17,27,28] met the inclusion requirement for the meta-analysis and the remaining studies [16,24-26] were excluded from the meta-analysis. One of the included studies [17] did not measure the mean percentage of non-mineralised tissue and thus two studies were included in the meta-analysis of non-mineralised tissue and three studies were included in the meta-analysis of newly formed bone. Random effect analysis and test for heterogeneity was inconclusive due to the limited number of studies included. No statistically significant difference in heterogeneity between the included studies was found for newly formed bone ( $I^2 = 0\%$ ,  $P = 0.803$ ) [17,27,28], and non-mineralised tissue ( $I^2 = 49\%$ ,  $P = 0.14$ ) [27,28]. Meta-analysis showed a mean difference of newly formed bone of 6.4% (confidence interval [CI] = 0 to 12.9) (Figure 2) and non-mineralised tissue of -1.1% (CI = -2.7 to 0.5) (Figure 3) demonstrating no statistically significant differences in newly formed bone and non-mineralised tissue after MSFA with or without barrier membrane coverage of the lateral window. However, MSFA with barrier membrane coverage of the lateral window seems to be associated with an overall higher percentage of newly formed bone and diminish non-mineralised tissue compared with the use of no barrier membrane coverage.

## Summary

Histomorphometric evaluation revealed no statistically significant differences in percentage of newly formed bone and non-mineralised tissue after MSFA with or without barrier membrane coverage of the lateral window. However, a higher percentage of



**Figure 2.** Meta-analysis using a random effect model assessing newly formed bone.



**Figure 3.** Meta-analysis using a random effect model assessing non-mineralised tissue.

newly formed bone and diminished non-mineralised tissue was observed with barrier membrane coverage of the lateral window compared with no barrier membrane coverage.

### Biologic and mechanical complications

Mucosal tears were observed in five patients after MSFA [24]. No information was provided about the mucosal tears were related to the use of barrier membrane coverage of the lateral window [24].

Biologic complications involving soft tissue wound dehiscence and unexplained postoperative swelling was described in two patients after MSFA without barrier membrane coverage of the lateral window [26]. The complications were solved with antibiotic treatment [26].

Sinus membrane perforation occurred in both groups and was successfully treated with a resorbable collagen membrane [27]. Mild haematoma and soft tissue wound dehiscence also occurred in both groups. There was no difference in the frequency of biologic complications between the two treatment modalities [27].

Unexplained pain occurred in three patients that resolved after treatment with Clindamycin [28]. Partial loss of grafting material into the subcutaneous space of the maxillary ridge occurred in four patients after MSFA without barrier membrane coverage of the lateral window [28].

### Summary

Biologic and mechanical complications after MSFA were not reported in all included studies, but when reported, they were generally infrequent and not severe. Perforation of the sinus membrane was the most frequent intraoperative complication, but this does not seem to influence the final implant treatment outcome. Frequency of mucosal tears and soft tissue wound dehiscence seem to be comparable between the two treatment modalities. However, displacement of the grafting material into the subcutaneous space was only reported after MSFA without barrier membrane coverage of the lateral window.

### Quality assessment

The quality of the included studies is summarised in Table 3. The controlled trial was characterised by high risk of bias [25]. Two randomised controlled trials were characterised by low risk of bias [26,27], one with moderate risk of bias [28], and three with high risk of bias [16,17,24].

### DISCUSSION

The objective of the present systematic review and meta-analysis was to test the hypothesis of no difference in implant treatment outcomes after MSFA with or without barrier membrane coverage of

**Table 3.** Quality assessment of included studies

Study	Random selection in the population	Definition of inclusion and exclusion criteria	Report of losses to follow-up	Validated measurements	Statistical analysis	Risk of bias
Froum et al. [16]	Yes	Yes	No	Yes	No	High
Tarnow et al. [17]	Yes	Yes	No	Yes	No	High
Tawil et al. [24]	Yes	Yes	No	Yes	No	High
Wallace et al. [25]	No	Yes	No	Yes	No	High
Choi et al. [26]	Yes	Yes	Yes	Yes	Yes	Low
Barone et al. [27]	Yes	Yes	Yes	Yes	Yes	Low
García-Denche et al. [28]	Yes	Yes	No	Yes	Yes	Moderate

the lateral window. The electronic search and hand-searching resulted in 1068 entries. One controlled trial [25] with high risk of bias and six randomised controlled trials [16,17,24,26-28] characterised by low [26,27], moderate [28] and high risk of bias [16,17,24], fulfilled the inclusion criteria and were included in the final synthesis.

The result of the present systematic review and meta-analysis demonstrated no statistically significant difference in implant survival rate, newly formed bone or non-mineralised tissue after MSFA with or without barrier membrane coverage of the lateral window. However, barrier membrane coverage of the lateral window generally increases the percentage of newly formed bone and diminishes proliferation of non-mineralised tissue. Thus, MSFA with barrier membrane coverage of the lateral window seems to be beneficial and improve bone regeneration. However, considerable variations in study design, small patient samples and type of outcome measures as well as various methodological confounding factors posed serious restrictions to review the literature in a quantitative systematic manner. Hence, the conclusions drawn from the results of the present systematic review should be interpreted with extreme caution and well-designed randomised controlled trials with larger patient samples are needed before definite conclusions can be provided about the effectiveness of barrier membrane coverage of the lateral window in conjunction with MSFA.

The included studies of the present systematic review revealed a tendency towards higher percentage of newly formed bone and diminished non-mineralised tissue after MSFA with barrier membrane coverage of the lateral window compared with no barrier membrane coverage [16,17,25-28]. Moreover, soft tissue adherence to the graft particles and infiltration of connective tissue into the grafting material was reported after MSFA without barrier membrane coverage of the lateral window [26]. However, the histomorphometric outcome after MSFA with or without barrier membrane coverage are influenced by numerous factors including the dimension of the lateral window, volume of the maxillary sinus cavity, type of grafting material and the residual alveolar bone height [34-36]. A statistically significant higher percentage of newly formed bone and diminished non-mineralised tissue have been reported after MSFA with reduced dimension of the lateral window compared with larger dimension [34]. In the present systematic review, the dimension of the lateral window was measured in one of the included studies demonstrating higher percentage of newly formed bone and diminishes non-

mineralised tissue with barrier membrane coverage compared with no membrane coverage, when the dimension of the lateral window was equivalent [27]. Consequently, the histomorphometric outcome is improved after MSFA with barrier membrane coverage when the dimension of the lateral window is equivalent.

Recent studies have demonstrated that the percentage of newly formed bone is inversely proportional to the bucco-palatal distance of the maxillary sinus. Thus, the volume of the maxillary sinus cavity also influences the amount of bone regeneration [36-39]. However, none of the included studies of the present systematic review evaluated the dimension of the maxillary sinus cavity or standardised the quantity of the grafting material.

A recent systematic review and meta-analysis assessing histomorphometric variables after MSFA concluded that autogenous bone graft revealed the highest amount of newly formed bone compared with other grafting materials [35]. The included studies of the present systematic review used dissimilar grafting materials and the histomorphometric outcome are thus not factual comparable. Consequently, histomorphometric outcome after MSFA is influenced by several confounding factors, which is not taken into account in the present systematic review.

A newly published retrospective study concluded that MSFA with barrier membrane coverage of the lateral window diminishes postoperative displacement of the grafting material and prevents bone substitutes particles from penetrating within the buccal mucosa [40]. One of the included studies of the present systematic review reported displacement of the grafting material into the subcutaneous space after MSFA without barrier membrane coverage [28]. Haemorrhage and swelling of the Schneiderian membrane after MSFA combined with the physiologically positive air pressure of the maxillary sinus may cause displacement of the grafting material through the lateral window, if the lateral window is left uncovered [28,40]. Thus, it is important that patients are instructed not to blow their nose and sneeze with open mouth after MSFA without barrier membrane coverage of the lateral window.

Changes in Schneiderian membrane thickness after MSFA have previously been assessed by cone beam computed tomography demonstrating a transient swelling of the Schneiderian membrane, which reaches the highest value one week after surgery and completely resolves over months [41,42]. The use of a larger graft volume was positively correlated with an increase in postoperative Schneiderian membrane

thickness [41]. Moreover, a recent computed tomographic study demonstrated that displacement of the grafting material was also influenced by the used volume of the grafting material [40]. Consequently, MSFA without barrier membrane coverage of the lateral window is associated with an increased risk of postoperatively displacement of the grafting material due to transient swelling of the Schneiderian membrane, size of the lateral window and volume of the grafting material. Thus, membrane coverage of the lateral window seems to stabilise and prevent displacement of the grafting material.

Systematic reviews provide a meticulous summary of the current evidence related to a research question or hypothesis. Meta-analysis is the statistical synthesis of the results included in the systematic review. The strength of evidence from a systematic review and meta-analysis is therefore related to the quality of the included studies. High quality randomised controlled trials with low risk of bias provide the highest level of evidence for ascertaining the safety and efficacy of a specific surgical intervention. The histomorphometric outcome of the present systematic review and meta-analysis is based on one randomised controlled trials with low risk of bias [27], one with moderate risk of bias [28], and one with high risk of bias [17]. Consequently, the current level of evidence is inadequate to propose implications for evidence based clinical guidelines according to the focus question of the present systematic review.

## CONCLUSIONS

The present systematic review and meta-analysis revealed no statistically significant difference in implant treatment outcomes after maxillary sinus floor augmentation with or without barrier membrane coverage of the lateral window. However, barrier membrane coverage increases percentage of newly formed bone, diminish proliferation of non-mineralised tissue and prevent displacement of the grafting material. Thus, barrier membrane coverage of the lateral window seems to be beneficial and improve implant treatment outcomes. However, small patient samples, dissimilar evaluation methods, different outcome measures and various methodological confounding factors posed serious restrictions reviewing the literature in a quantitative systematic manner. Hence, the conclusions drawn from the results of the present systematic review should be interpreted with extreme caution and well-designed randomised controlled trials that follow Consolidated Standards of Reporting Trials (CONSORT) guidelines are needed before definite conclusions can be provided about the effectiveness of barrier membrane coverage of the lateral window.

## ACKNOWLEDGMENTS AND DISCLOSURE STATEMENTS

The authors report no conflicts of interest related to this study.

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**Appendix 1.** PRISMA checklist [22]

Section/topic	#	Checklist item	Reported on page #
<b>TITLE</b>			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
<b>ABSTRACT</b>			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
<b>INTRODUCTION</b>			
Rationale	3	Describe the rationale for the review in the context of what is already known.	4
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	4,5
<b>METHODS</b>			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	6
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	6,7,9
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	7,8
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	8
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	8,9
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	9,10
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	10
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	10,11
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	Not reported
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., $I^2$ ) for each meta-analysis.	12,13
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	Not reported
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	Not reported
<b>RESULTS</b>			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	13
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	13-15
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	21
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	15-21
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	18,19
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	21
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	Not reported
<b>DISCUSSION</b>			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	21
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	21,22
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	24,25
<b>FUNDING</b>			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	25

**Appendix 2.** PubMed search until the 5<sup>th</sup> of July, 2019

Search	Add to builder	Query	Items found
#48	Add	Search (((Osteotomy[tw] OR lateral[tw] OR window[tw])) AND (((“Sinus Floor Augmentation”[Mesh]) OR (((“Maxillary Sinus”[Mesh]) OR Maxillary Sinus[Text Word]) OR sinus floor[Text Word])) AND ((“Bone Transplantation”[Mesh]) OR ((transplant*[Text Word] OR augmentat*[Text Word] OR elevat*[Text Word] OR graft*[Text Word] OR lift*[Text Word]))))) AND membrane*[Text Word]))	469

**Appendix 3.** Embase search until the 5<sup>th</sup> of July, 2019

No.	Query	Results
#15	#10 AND #13 AND #14	442
#14	osteotomy:ti,ab,kw,de OR lateral:ti,ab,kw,de OR window*:ti,ab,kw,de	512091
#13	#11 OR #12	1381887
#12	‘artificial membrane’/exp	47221
#11	membrane*:ti,ab,kw,de	1380557
#10	#1 OR #9	3339
#9	#5 AND #8	3339
#8	#6 OR #7	1939869
#7	transplant*:ti,ab,kw OR augmentat*:ti,ab,kw OR graft*:ti,ab,kw OR elevat*:ti,ab,kw OR lift*:ti,ab,kw	1920983
#6	‘bone transplantation’/exp	51406
#5	#2 OR #3 OR #4	17891
#4	(sinus NEAR/2 floor):ti,ab,kw,de	2001
#3	((maxilla* OR maxillar*) NEAR/2 sinus):ti,ab,kw,de	17442
#2	‘maxillary sinus’/exp	12055
#1	‘sinus floor augmentation’/exp	991

**Appendix 4.** Cochrane Library search until the 5<sup>th</sup> of July, 2019

ID	Search	Hits
#1	MeSH descriptor: [Sinus Floor Augmentation] explode all trees	134
#2	((maxilla* OR maxillary) NEAR/2 Sinus)	613
#3	sinus NEAR/2 floor	338
#4	#2 OR #3	712
#5	MeSH descriptor: [Bone Transplantation] explode all trees	886
#6	transplant* OR augmentat* OR graft* OR elevat* OR lift*	108626
#7	#5 OR #6	108626
#8	#4 AND #7	456
#9	#1 OR #8	456
#10	MeSH descriptor: [Membranes, Artificial] explode all trees	1174
#11	membrane*	16574
#12	#10 OR #11	16908
#13	osteotomy OR lateral OR window*	20494
#14	#9 AND #13 AND #13	156